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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|----------------------|------------------|
| 09/655,815 | 09/06/2000 | Robert Lanza | P 0275705 23523-0162 | 8460 |

909 7590 07/01/2003
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EXAMINER

TON, THAIAN N

ART UNIT PAPER NUMBER

1632

21

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/655,815

Applicant(s)

LANZA ET AL.

Examiner

Thai-An N. Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 04 June 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-7 and 11-14.

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' argue that the claims as presently amended overcome the prior rejection for the following reasons: 1) with regard to an explicit activation step, Applicants argue that it would be clear to those skilled in the art that the initial NT step is effected under conditions that result in the generation of an embryo and that this process may include" an activation step that promotes the development of the NT unit into an embryo. 2) with regard to the specification's lack of teaching or guidance with respect to the evaluation of immune compatibility, Applicants argue that the specification clearly describes various well-known means for evaluating immune responses to transplanted tissues or cells.

Applicants' arguments have been considered but are not found to be persuasive. Firstly, the Examiner has clearly shown that those of skill in the art support that activation of the NT unit is required (not optional) in order for the NT unit to develop into an embryo. Furthermore, as the claims require the generation of an embryo, an activation step is required for the methods to be enabled. Secondly, although the specification discusses general methods to test immune compatibility in NT-generated cells in cattle, the specification does not provide teachings or guidance to show how cattle carrying teratomas would be tested for immune compatibility. Accordingly, the rejection is maintained for reasons of record advanced on pages 5-8 of the prior Office action.

CORRECTION OF PATENTS

1490

T. D. INFORMAL MEMO: DO NOT MAIL THIS MEMO TO APPLICANT

DATE: 6/10/03TO: EXAMINER TOW

FROM: _____

APPL. S.N.: 09/655,815ART UNIT: 1632SUBJECT: Decision on Terminal Disclaimer (T.D.) filed: 6/4/03

INSTRUCTIONS: I have reviewed the submitted T.D. with the results as set forth below. If you agree, please use the appropriate form paragraphs identified by this informal memo in your next Office action to notify applicant of the T.D. If you disagree or have any questions, please see me or the Special Program Examiner. THIS IS AN INFORMAL, INTERNAL MEMO ONLY. IT MUST NOT BE (1) MAILED TO APPLICANT OR (2) PLACED OF RECORD IN THE APPLICATION FILE. When your action is complete, please initial, date and return this memo to me. THANK YOU.

- ☒ The T.D. is PROPER and has been recorded (see ¶14.23).
- ☐ The T.D. is NOT PROPER and has not been accepted for the reason(s) checked below (see ¶14.24):
- ☐ The recording fee of \$ _____ has not been submitted nor is there any authorization in the application file for the use of a deposit account (see ¶14.26.07).
 - ☐ The T.D. does not satisfy Rule 321 in that the person who has signed the T.D. has not stated the extent of his/her interest (and/or the extent of the interest of the business entity represented by the signature) in the application/patent (see ¶¶14.26 & 14.26.01).
 - ☐ The T.D. lacks the enforceable only during common ownership clause - needed to overcome a double patenting rejection, Rule 321(b) (see ¶14.27.01).
 - ☐ The T.D. is directed to a particular claim(s), which is not acceptable since "the disclaimer must be a terminal portion of the term of the entire patent to be granted." (MPEP 1490) (see ¶¶14.26 & 14.26.02).
 - ☐ The person who signed the T.D.:
 - ☐ is not an attorney "of record" (see ¶¶14.29 and 14.29.01).
 - ☐ has failed to state his/her capacity to sign for the business entity (see ¶14.28).
 - ☐ is not recognized as an officer of the assignee (see ¶¶14.29 & possibly 14.29.02).
 - ☐ No documentary evidence of a chain of title from the original inventor(s) to assignee has been submitted, nor is the reel and frame number specified as to where such evidence is recorded in the Office (see 37 CFR 3.73(b) and 1140 O.G. 72). NOTE: This documentary evidence or the specifying of the reel and frame number may be found in the T.D. or in a separate paper of record in the application (see ¶14.30).
 - ☐ The T.D. is not signed (see ¶¶14.26 & 14.26.03).
 - ☐ The serial number of the application (or the number of the patent) which forms the basis for the double patenting rejection is missing or incorrect (see ¶14.32).
 - ☐ The serial number of this application (or the number of the patent in reexam or reissue cases being disclaimed is missing or incorrect (see ¶¶14.26, 14.26.04 or 14.26.05).
 - ☐ The period disclaimed is incorrect or not specified (see ¶¶14.26, 14.27.02 or 14.27.03).
 - ☐ Other: _____
 - ☐ Suggestion to request refund (see ¶14.36). NOTE: If already authorized, credit refund to deposit account and do not check this item.

I have appropriately notified applicant(s) of the status of the Terminal Disclaimer filed in this case.

Ex. Initials: _____ Date: _____

RETURN THIS MEMO TO _____

(Rev. 5/98)